REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 36-70, including independent claims 36, 54, and 67, are pending in the present application. Independent claim 36, for instance, is directed to an elastomeric article that comprises a substrate body, a chemical protection layer that overlies an outside surface of the substrate body, and an optional outer layer that overlies the chemical protection layer. The substrate body includes a layer made of at least one elastomeric block copolymer, such as a styrene-ethylene-butylene-styrene (S-EB-S) triblock copolymer. The chemical protection layer of the elastomeric article of claim 36 is formed from a polymeric material that consists essentially of at least one crosslinked, modified silicone elastomer. The crosslinked, modified silicone elastomer imparts relative chemical resistance to the elastomeric article.

Applicants' specification describes how elastomeric articles formed from certain types of synthetic polymers tend to dissolve when contacted with certain chemicals or solvents, such as bone cement. (Appl., p. 1, lines 8-18). The presently claimed elastomeric articles and elastomeric gloves, then, include a chemical protection layer that will not substantially dissolve when contacted with certain chemicals or solvents. (Appl., p. 4, lines 15-18; p. 8, lines 14-16).

In the Office Action, claims 36-70 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Office Action stated that the recitation "consists essentially of" in independent claims 36, 54,

and 67 "is deemed new matter" and that the specification, as originally filed, "does not provide support for the invention as is now claimed." (Office Action, at 3).

A "consists essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format. (See MPEP, § 2111.03). The transitional phrase "consists essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. Id. In this case, the claims require that the chemical protection layer is formed from a polymeric material that "consists essentially of" at least one crosslinked, modified silicone elastomer. Thus, although the polymeric material may contain certain minor ingredients (e.g., fillers, processing aids, additives, pigments, etc.), the claims specifically exclude the presence, in the polymeric material of the chemical protection layer, of materials that would materially affect the basic and novel characteristics of the claimed invention.

Regarding the assertion in the Office Action that using the phrase "consists essentially of" constitutes new matter, Applicants respectfully submit that the specification, as originally filed, contains embodiments wherein the chemical protection layer is formed from a polymeric material that "consists essentially of" at least one crosslinked, modified silicone elastomer. By way of illustration only, in the Example at pages 18-20, the chemical protection layer was formed from a polymeric material that included only a crosslinked, modified silicone elastomer, specifically, MED 10-6640, available from NuSil Technologies. Therefore, Applicants respectfully submit that the

claims of the present application satisfy the requirements of 35 U.S.C. § 112, first paragraph.

In the Office Action, independent claims 36, 54, and 67 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,302,852 to Joung in view of U.S. Patent No. 5,792,531 to Littleton, et al. Joung is directed to a glove that may include (1) an allergenic elastomeric support glove (made of natural rubber latex), (2) a barrier glove of a nonallergenic elastomer (such as a room-temperature vulcanizing (RTV) silicone elastomer) bonded to the inner surface of the support glove, and (3) a slip resistant glove of an elastomer (such as an RTV silicone elastomer) bonded to the external surface of the glove. Joung's glove is designed to provide a nonallergenic layer on the inside of the glove that contacts a user's hand so that irritation commonly caused by natural rubber latex gloves is reduced. Joung's glove is also designed to substantially reduce the amount of lubricating donning powder used in comparison to the amount typically used with natural rubber latex gloves. Joung further states that its gloves are able to withstand cracking and delamination that may be caused by sharp angular flexing in the knuckle area as well as the stretching and snapping that occurs during donning.

As correctly noted in the Office Action, Joung fails to teach various aspects of independent claims 36, 54, and 67. For example, Joung fails to teach or suggest an elastomeric article or glove whose substrate body includes a layer made of at least one elastomeric block copolymer, such as an S-EB-S triblock copolymer. Nevertheless, Littleton, et al. was combined with Joung in an attempt to render independent claims 36, 54, and 67 unpatentable.

Littleton, et al. is directed to elastomeric, powder-free articles having improved donning characteristics. More particularly, Littleton, et al. describes an elastomeric article, such as a glove, that may include a substrate body made of a mid block saturated styrene block copolymer (such as an S-EB-S block copolymer). The elastomeric articles of Littleton, et al. further include a donning layer overlying at least one side of the substrate body, wherein the donning layer comprises a chlorinated mid block unsaturated block copolymer (such as a chlorinated styrene diene block copolymer). The elastomeric articles of Littleton, et al. preferably have excellent elastic and strength properties, are hypoallergenic, are resistant to environmental degradation (such as ozonation), and can be donned easily without the presence of any lubricating powder.

In combining Joung with Littleton, et al., the Office Action stated that Joung discloses a substrate body and a chemical protection layer that includes at least one crosslinked, modified silicone elastomer, and that Littleton, et al. discloses that the substrate body may contain at least one styrene-ethylene-butylene-styrene (S-EB-S) triblock copolymer. The reason for combining these references was said to be that "it is old and well-known in the analogous art to have an elastomeric glove wherein the substrate body contains a styrene-ethylene-butylene-styrene triblock copolymer . . . for the purpose of producing a hypoallergenic elastomeric glove with excellent elastic and strength properties." The Office Action further stated:

> Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have modified the elastomeric material of the substrate body in Joung to consist of a styrene-ethylene-butylene-styrene triblock copolymer as suggested by Littleton et al. in order to produce a hypoallergenic

> elastomeric glove with excellent elastic and strength properties and [that] is resistant to environmental degradation such as ozonation.

(Office Action, at 4-5). Applicants respectfully disagree.

In particular, Applicants respectfully submit that there would have been no motivation or suggestion for one of ordinary skill in the art to combine Joung with Littleton, et al. in the manner proposed in the Office Action. The entire premise of Joung revolves around its elastomeric support glove being made from an "allergenic" material (specifically, natural rubber latex). A significant part of what Joung considers to be its "invention" is bonding a barrier glove containing a nonallergenic elastomer to the inner surface of the allergenic support glove to render the entire glove "hypoallergenic." Thus, clearly, no suggestion or teaching exists within Joung that Joung's "allergenic elastomeric support glove" should be made of at least one elastomeric block copolymer (like an S-EB-S triblock copolymer).

Applicants note that the level of skill in the art cannot be properly relied upon to provide the suggestion to combine references. (See, e.g., MPEP § 2143.01). Moreover, a statement that modifications of the prior art to meet the claimed invention would have been well within the ordinary skill of the art at the time the claimed invention was made because the references relied upon teach that all aspects of the claimed invention were individually known in the art is also not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

In the instant case, the Office Action indicates that it is "old and well-known" to use S-EB-S copolymers to manufacture gloves. Even if true, no motivation or

suggestion would have been provided to utilize the particular elastomeric block copolymer of Littleton, et al. in Joung. Instead, it appears that the only rationale is based on the notion that it would have been "obvious to try" such an elastomeric block copolymer, which is improper under 35 U.S.C. § 103(a). Accordingly, Applicants respectfully submit that independent claims 36, 54, and 67 patentably define over Joung and Littleton, et al., as no motivation or suggestion would have existed for one of ordinary skill in the art to combine these references as proposed by the Office Action.

Independent claims 36, 54, and 67 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0 069 387 B1 to Nash in view of Littleton, et al. Nash is directed to a surgical glove having a textured outer surface obtained by the following steps: (a) providing a one or two part dispersion of silicone elastomer in an organic solvent by adding hydrophilic silica to a dispersion of silicone elastomer in the organic solvent, (b) providing a coating of the dispersion obtained in step (a) onto the outer surface of a surgical glove, and (c) curing the coating to obtain a surgical glove having a textured outer surface. The hydrophilic silica added in step (a) has a particle size of about 2-10 microns, a specific surface area of about 75-200 m^2/g, and a density such that the particles float in the elastomer and thereby migrate to the surface.

The Office Action correctly pointed out that Nash fails to disclose certain features of Applicants' claimed invention, for example, an elastomeric article or glove whose substrate body includes a layer made of at least one elastomeric block copolymer (such as an S-EB-S triblock copolymer). Nevertheless, Littleton, et al. was combined with Nash in an attempt to render obvious claims 36, 54, and 67. Specifically, the Office Action stated:

> Littleton et al. teaches that it is old and well-known in the analogous art to have an elastomeric glove wherein the substrate body contains a styrene-ethylene-butylene-styrene triblock copolymer . . . for the purpose of producing a hypoallergenic elastomeric glove with excellent elastic and strength properties and [that] is resistant to environmental degradation such as ozonation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have modified the substrate body of the glove in Nash to consist of a styrene-ethylene-butylene-styrene triblock copolymer as suggested by Littleton et al. in order to produce a hypoallergenic elastomeric glove with excellent elastic and strength properties and [that] is resistant to environmental degradation such as ozonation.

(Office Action, at 9). Applicants respectfully disagree.

Nash generally states that its texturing process is applicable to "surgical gloves," including both "silicone and non-silicone gloves." However, nothing in Nash teaches or suggests that it is desirable to texture gloves that include a substrate body made from at least one elastomeric block copolymer, such as an S-EB-S triblock copolymer. Rather, it appears that the Examiner's only incentive or motivation for combining Littleton, et al. with Nash results *improperly* from using Applicants' disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art.

Littleton, et al.—with its description of elastomeric gloves that may include (1) a substrate body made of an S-EB-S block copolymer, and (2) a donning layer overlying the substrate body—actually gives rise to the very problem Applicants seek to solve in the present application. That is, Applicants have recognized that elastomeric articles formed from polymers like S-EB-S block copolymers may dissolve when contacted with certain chemicals or solvents, such as bone cement. Thus, Applicants are claiming an elastomeric article or glove that includes a chemical protection layer overlying the

outside surface of the article or glove's substrate body so that relative chemical resistance is imparted to the elastomeric article or glove.

Applicants respectfully submit that no suggestion or motivation whatsoever—whether explicit or implicit—exists in either of these references for combining the teachings of Littleton, et al. with Nash and arriving at an elastomeric article or glove having the features set forth in independent claims 36, 54, and 67. Applicants emphasize that a determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. Therefore, Applicants respectfully submit that independent claims 36, 54, and 67 patentably define over the above-cited references, taken singularly or in any proper combination.

Dependent claims 37-53, 55-66, and 68-70 were also rejected using the above-identified references and/or U.S. Patent Nos. 5,534,350 to Liou and 6,730,380 to Littleton, et al.[1] Applicants respectfully submit that at least for the reasons indicated above relating to independent claims 36, 54, and 67, the dependent claims also patentably define over the cited references. The patentability of the dependent claims, however, certainly does not hinge on the patentability of independent claims 36, 54, and 67. In particular, some or all of dependent claims 37-53, 55-66, and 68-70 are believed to possess features that are independently patentable, regardless of the patentability of claims 36, 54, and 67.

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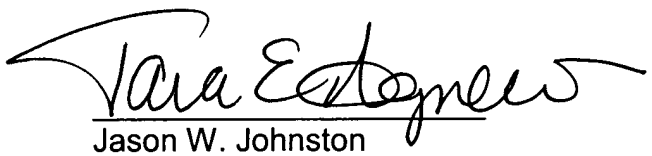
[1] Applicants again note that Littleton, et al. was published on May 4, 2004 and is thus not prior art to the present application under 35 U.S.C. § 102(b). Nevertheless, Applicants wish to bring WO/0009320 to the attention of the Examiner, which is the corresponding PCT application of U.S. Patent No. 6,730,380 (published on February 24, 2000).

In summary, Applicants respectfully submit that the present claims patentably define over the prior art of record for at least the reasons set forth above. As such, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Simone is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

DORITY & MANNING, P.A.



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